GOLDBELT RAVEN LLC

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Healthcare Staffing Biomedical Research IT Solutions

Medical Equipment Regulatory Compliance

A Partnership for Success

Making a Difference in 8(a) Contracting, One Customer at a Time

Goldbelt Raven

MEDCOM

GOLDBELT RAVEN LLC

Overview

Making a Difference in 8(a) Contracting, One Customer a Time

- **Goldbelt Raven, LLC** is an Alaskan Native Corporation owned, certified Small Disadvantaged Business (ANC 8(a))

- **Goldbelt Raven, LLC** is a Mission Driven, Government Focused and Employee Centered Firm established in 2001

- **Goldbelt Raven, LLC** has its Corporate Headquarters in Juneau, Alaska with Federal Offices in Chantilly, VA and Frederick, MD

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Simplified Acquisition

Fast, Simple & Compliant

- **8(a) ANC's can receive Sole Source Awards with NO Competition, NO Prior Advertisement and NO Protest.**
- **8(a) ANC's can be awarded contracts with no upper ceiling based upon the maximum estimate of the requirement.**

{1}13 C.F.R. 124.506(b): SBA may award a sole source 8(a) contract to a Participant concern owned and controlled by an Indian tribe or an ANC where the anticipated value of the procurement exceeds the applicable competitive threshold if SBA has not accepted the requirement into the 8(a) BD program as a competitive procurement. There is no requirement that procurement must be competed whenever possible before it can be accepted on a sole source basis for a tribally owned or ANC- owned concern, but a procurement may not be removed from competition to award it to a tribally owned or ANC-owned concern on a sole source basis.

{1}13 C.F.R. 124.517(a), which states: "The eligibility of a Participant for a sole source or competitive 8(a) contract may not be challenged by another Participant or any other party, either before SBA or any administrative forum as part of a bid or other contract protest."

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Core Capabilities

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- Healthcare Staffing and Services
- Medical Equipment Procurement
- Medical Transcription
- Clinical Research
- Regulatory Compliance
- Biomedical Research Services
- Information Technology Solutions

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Services

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- Physicians
- Nurses
- Dentists
- Physician Assistants
- Pharmacists
- Laboratory Technicians
- Physical Therapists
- Respiratory Therapists
- Medical Technologists
- Phlebotomists
- Clinical Social Workers
- Radiological Technicians
- Occupational Health Specialists
- Home Health Aides
- Medical Transcription
- Medical Data Warehousing Staffing
- HIPAA Compliance
- CLIA Certification
- Hospital Accreditation (JCAHO)
- Hospital administrators

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Clinical Research Staffing

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- Principal Investigators
- Medical Monitors
- CRCs
  - Study Site Research Nurse
  - Study Site Coordinator
- CRAs
  - Monitors
  - Project directors
- Lab Technicians
- Regulatory Nurses
- QA Auditors

- Regulatory Compliance
- Good Clinical Practice (GCP)
- ICH Compliance
- Human Subject Protection
- 21 CFR Part 11 Compliance
- Clinical Data Management System Implementation
- Electronic Data Management System Implementation

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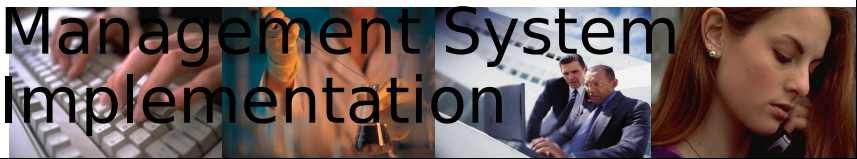

Contracts

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- Indemnification of - Physicians
  - Nurses
  - other HCPs
  → ❖ Eliminates need for malpractice insurance
  - Govt. self-insures
  - Lowers costs
- Single contract → ❖ Saves time and internal staffing
- National Recruitment → ❖ Saves labor, time, cost
- Certification → ❖ Assures high quality

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Regulatory Compliance

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- Regulatory Compliance
- Report Writing (ICH)
- Pre-IND meetings
- Preparation of INDs
- Pre-NDA meetings
- Preparation of NDAs
- Regulatory Filing
- Human Subject Protection
- GXP
  - GLP
  - GCP
  - GMP
  - GXP Auditing
- 21 CFR Part 11 Compliance
- Clinical Data Management System (CDMS) Implementation
- Electronic Data Management System (EDMS) Implementation

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Services

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- Research Scientists
  - Microbiologists
  - Immunologists
  - Virologists
  - Bacteriologists
  - Veterinarians
  - Physiologists
  - Biochemists
  - Pathologists
  - Neuroscientists
  - Toxicologists
  - Physicists
  - Chemists
- Laboratory Technicians
  - Proteomics
  - Genomics
  - Microbiological techniques
  - Biochemists
  - Cell Culture
  - Sterility/potency assays
  - GC/MS, HPLC
- Animal Handlers
- Laboratory Administrators
- Administrative Assistants

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Aquisition

Making a Difference in 8(a) Contracting, One Customer at a Time

- **Simplifies acquisition of medical equipment**
- **Two contract vehicles**
  - **NIH Contract: Medical Equipment Group (MEG)**
    - ✓ Sole source contract awarded on 16FEB01 by NIH
    - ✓ 5 year Multi-Agency IDIQ (MAI) contract – base year, 4 options
    - ✓ Medical equipment (hospital/clinical, research, dental, veterina and
      Medical Information Systems/Equipment) – FSC Codes 65 and
    - ✓ Contract ceiling: $1 B per year
  - **USAMRAA Contract: Army Research Medical Equipment and Consumables (ARMEC)**
    - ✓ Sole source contract awarded on 26JUL04 by USAMRAA
    - ✓ 5 year Multi-Agency IDIQ (MAI) contract - base year, 4 options
    - ✓ Medical equipment and consumables (hospital, research, laboratory,
      clinic, dental, veterinary)
    - ✓ Contract ceiling: $325 M over 5 years

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ARMEC

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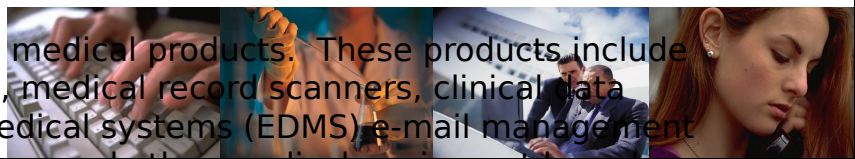
Goldbelt shall deliver efficient, innovative, and cost-effective acquisition of:

- **Hospital equipment**
  Full range of equipment for hospitals, medical centers, specialty clinics and research facilities ranging from preventative, diagnostic, curative, rehabilitative and long term care to address patient needs, etc.
- **Dental equipment**
  Chairs, evacuators and operatories, lasers, coagulators, sterilizers hand pieces, burrs and polishers, dental x-ray equipment, film processors, image intensifiers, etc.
- **Ophthalmologic equipment**
  Fundus cameras, slit lamps, laser refractors, polishers, ultrasonic cleaners, operating room microscopes, etc.
- **Medical & radiological equipment**
  Cardiac and neonatal monitoring systems, telemetry systems, CT, MRI and PET imaging devices, surgical tables and equipment, emergency room systems, heart-lung bypass, kidney and peritoneal dialysis systems, etc.
- **Research equipment**
  Laboratory research equipment, desks, chairs, filing cabinets, telephone switching systems, clinical gas and water delivery and monitoring systems, medical hazardous waste disposal systems, etc.
- **Medical information equipment**
  High technology devices and solutions integral to medical products. These products include patient information systems, nurses workstations, medical record scanners, clinical data management systems (CDMS), electronic data medical systems (EDMS), e-mail management



ARMEC

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- **For use by all federal agencies**
- **Broad equipment selection** - We work with over 500 vendors, constantly adding new ones in order to provide specialized equipment and a wide variety of options
- **8(a) credit** - for all orders processed via MEG
- **Quotes involve a Price Analysis Process**. Relevant documentation can be provided as requested or required
- **With ARMEC** – Can order durable equipment and/or consumables
- **With MEG** – Can order applicable consumables with each capital equipment order

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Contracts

Past Performance

- **<u>U. S. Army Medical Research Institute of Infectious Diseases</u>**
- Contract DAMD17-03-0017
- Awarded September 22, 2003 – Value $80 Million
- R&D efforts to develop strategies, products, information,
- Against biological warfare threats and infectious diseases
- Lead Research Laboratory – Biological Defense
- Largest bio-containment Lab in the United States
- Biological Warfare – Infectious Disease Research
- Procedures, and training programs for medical

Contracts

Past Performance

- **<u>Directorate of Information Management (DOIM) – Ft. Detrick</u>**
- Contract DAMD17-03-R-0029 Value - $40 Million
- Awarded August 22, 2003 – 5 Year Contract
- Network Engineering/Network Management
- Program Management/Project Management
- Earned Value Management
- 140 Server Farm
- IBM Mainframe – Migration to Z Box Server
- Web Development – 100 Sites
- Help Desk

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Contracts

Past Performance

- **<u>Marine Corp Systems Command</u>**
- Contract N00019-03-0018
- Awarded January 15, 2004
- Contract Value $1.5 Million
- Program Management/Project Management
- Implementation of Oracle E-Business Solution
- Oracle Customization
- Paperless Budgeting Process Implementation
- Planning, Programming, Budgeting Modules
- Systems Administration

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Contracts

Past Performance

- **<u>U. S. Army Medical Research Institute of Infectious Diseases</u>**
- DAMD17-03-0056
- Awarded December 2003 – Value $1.5 Million
- Implementation/Integration of Clinical Trials Software

  -Supporting Bio-Defense Special Immunization Program
- Computer Validation – FDA Mandated Process
- Network Management/Server Management
- Oracle Based Software – Customized
- 21 CFR Part 11 FDA Compliance

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